

Original Article

Comparison of the analgesic efficacy of expressed breast milk and 25% dextrose during the first hepatitis B vaccination

Hameed Uddin Ahmed¹, Praveen S. Sindhoor²

From ¹Junior Resident, ²Professor, Department of Paediatrics, K.V.G. Medical College and Hospital, Sullia, Karnataka, India

Correspondence to: Dr. Hameed Uddin Ahmed, Department of Paediatrics, K.V.G. Medical College and Hospital, Kurunjibhag, Sullia – 574 239, Karnataka, India. E-mail: i.am.hameed001@gmail.com

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ABSTRACT

Background: Injectable vaccines are a common source of pain and distress for newborn babies. Sweet-tasting solutions such as sucrose and 25% dextrose (25D) are described as effective strategies for pain relief in newborns. **Objective:** This study was done to compare the analgesic efficacy of expressed breast milk (EBM) and 25D solution during vaccination with hepatitis B (Hep B) vaccine at birth. **Materials and Methods:** This study was conducted at the vaccination clinic in the pediatrics department of a tertiary care hospital in southern India. The participants included healthy term babies and late preterm babies at the clinic during their routine dose of Hep B at birth, during the study period from June 2017 to December 2017. A total of 70 consecutive neonates were randomly allocated into two groups. 2 ml of either EBM or 2 ml of 25D solution was given 1 min before the injection. The outcome variables recorded were the duration of cry after injection and Neonatal Infant Pain Scale (NIPS) scores for both the groups. **Results:** The duration of cry was found to be slightly higher in the group receiving EBM than those receiving 25D, although it was not found to be statistically significant. The neonates in the 25D group had lower NIPS scores than those in the EBM group. **Conclusions:** 25D appears to be a slightly better analgesic when compared to EBM during Hep B injection at birth.

Key words: *Breastfeeding, Glucose, Neonatal, Pain management*

Newborn babies face acute pain with various medical procedures. The smallest of the babies feel pain, and this pain has serious consequences in later life [1]. Neuroendocrine systems and neuroanatomic components of the neonate are sufficiently developed to allow transmission of painful stimuli [2]. Recognition that both premature and full-term infants experience pain has led to increasing appreciation of the undertreatment of stress and pain of hospitalized infants. Recent evidence suggests that neonatal pain and stress influence neurodevelopment and affect later perceptions of painful stimuli and behavioral responses, and prevention and control of pain are likely to benefit infants.

Sick neonates are subjected to multiple painful blood samplings during their sojourn at the neonatal intensive care unit (NICU) added to the pain during airway insertions and plaster removals. Healthy neonates also have to go through the pain of injections in the first few days of life, namely the B.C.G vaccine and hepatitis B (Hep B) vaccine, in accordance with the National Immunization Schedule of India. Pain management during these injections is for the larger part, neglected at most centers. There are several strategies described to decrease pain at such visits such as direct breastfeeding or expressed breast milk (EBM), use of sweet-tasting solutions, and the facilitated tuck position. Various scales have also been described for the assessment of neonatal pain such as

Neonatal Infant Pain Scale (NIPS), Premature Infant Pain Profile (PIPP), and Modified Facial Coding Score (MFCS). Few studies have been done regarding analgesia at immunization clinics. This study was done to compare the analgesic efficacy of EBM and 25% dextrose (25D) at the time of the birth dose of Hep B vaccination.

MATERIALS AND METHODS

This study was conducted at the immunization clinic of a tertiary care hospital in southern India run jointly by the department of pediatrics and the department of community medicine. The study commenced in June 2017 and ended in December 2017. Written informed consent was taken from the parents of the participating neonates, and institutional ethical clearance was taken. Neonates were included in the study if they were healthy late preterm (>34 weeks gestational age) or term babies and were exclusively breastfed. Sick neonates admitted to NICU, neonates with birth asphyxia, or cardiorespiratory instability, and mothers on sedation, with difficult labor, and decreased milk output were excluded from the study.

A pre-structured pro forma was filled up for each neonate, which included the outcome variables used in our study and the other details of the neonate such as mother's name, birth weight, sex, gestational age, and intervention group. The birth rate of the

taluk was 13. It was decided to include all the neonates in the study who were delivered at the tertiary care hospital excluding those who belonged to the exclusion criteria. Thus, 70 eligible newborns were consecutively and equally allotted at birth either to the EBM group or the 25D group. The technique of the expression of breast milk was taught to the mothers of newborns in the EBM group. Approximately 2 ml of expressed milk was drawn up in a sterile dropper by a nurse before the procedure and brought to the immunization room. For the infants in the 25D group, 2 ml of commercially available 25D (100 ml solution from Fresenius Kabi) was used. The babies in both the groups were not breastfed from half an hour before till the injection was over. Both EBM and 25D were administered per orally 2 min before the injection at the immunization clinic by the nurse, using the pre-drawn droppers. All the babies were held in the classical holding position during the injection.

Before the study, one volunteer was trained in the assessment of the NIPS. The newborns were administered 0.5 ml of the Hep B injection on the anterolateral aspect of the right thigh after the skin was cleansed with spirit. The outcome variables noted were - duration of cry starting from the point of insertion of the needle and assessment of the NIPS score.

The duration of the cry was timed from the moment the injection pierced the skin of the baby till cessation of the cry. If the crying persisted for >180 sec, it was simply recorded as duration >180 sec. The NIPS is a scale for procedural pain in neonates and was developed in 1993 by Lawrence *et al.* [3] to evaluate the behavioral and physiological pain responses of preterm and term infants. It is a composite score of 6 parameters - facial expression, cry, breathing patterns, arms, legs, and state of arousal. The maximum score possible is 7 and minimum is 2. The NIPS is generally divided into mild pain (1–2/7), moderate (3–4/7), and severe pain (5–7/7). The NIPS scores were assessed by the trained volunteer for each neonate and the duration of the cry after vaccination was recorded to a maximum of 3 min (180 sec). The data were analyzed using IBM SPSS v. 25. Fisher's exact test and Chi-square tests were applied to see if there was a statistically significant difference between the two groups.

RESULTS

The study population consisted of 70 babies who were equally divided into two groups (i.e. 35 in each). In the EBM group, 16 (45.7%) babies were male and 19 (54.3%) were female; 24 (68.5%) were term babies and 11 (31.5%) babies were preterm. In the 25D group, 20 (57.1%) were male and 15 (42.9%) female; 27 (77.1%) term and 8 (22.9%) were preterm babies. The average birth weight was 2.71 kg in EBM group and 2.9 kg in the 25D group. In the EBM group, there were 25 babies of postnatal age <2 days and 10 babies of age >2 days. Similarly, in the 25D group, there were 23 babies younger than 2 days of age and 12 babies older than 2 days of postnatal age. The duration of the cry in both the groups is presented in Table 1 where the median duration of cry in the EBM group was 46.4 sec and 32.3 sec in 25D group.

In the EBM group, 21 newborns did not cry at all or ceased to cry within the 1st min, 10 newborns ceased to cry within 120 s, and three newborn ceased within 180 sec. One newborn's cry persisted for >180 sec. Likewise, in the 25D group, 25 newborns fell under the 0–60 sec cry duration subgroup, eight newborns in the 61–120 sec group, and two in the 121–180 sec group. A total of seven babies in EBM group had scores of NIPS of severe pain, 17 had scores of moderate pain, and 11 had mild pain. Four babies in 25D group had severe pain, 12 babies moderate pain, and 19 babies experienced mild pain ($p=0.14$, Chi-square - 3.8) (Table 2). Grimace was seen in 23 babies (65.7%) in the EBM group and 21 babies (60%) in the 25D group. Vigorous cry was seen in 14 babies (40%) in the EBM group and 10 babies (28.5%) in the 25D group (Table 3).

DISCUSSION

Numerous non-pharmacological interventions have been tried to reduce pain of vaccination. Sweet-tasting solutions such as sucrose and 25D have been used for analgesia in newborns as have been direct breastfeeding and EBM. A study by Osinaike *et al.* [4] showed that breastfeeding during venipuncture reduces pain in neonates. Similar analgesic effects of EBM were observed in studies by Upadhyaya *et al.* [5]

Sucrose is effective for reducing procedural pain from single events such as heel lance, venipuncture, and intramuscular injection in both preterm and term infants. An optimal dose of sucrose could not be determined due to inconsistency in effective sucrose dosage among studies [6]. Furthermore, sucrose solutions are not readily available across all NICUs and hospitals across developing nations like India. A review by Harrison *et al.* [7] showed sufficient evidence of the effectiveness of sweet-tasting solutions. In another study by Gradin *et al.* [8], comparing the analgesic effect of oral sucrose (30%) versus breastfeeding, shortly before the painful procedure, showed that a combination of oral glucose and breastfeeding showed the lowest pain

Table 1: Duration of cry in the two study groups

Duration of cry (s)	Study group	
	EBM	25D
0–60	21	25
61–120	10	8
121–180	3	2
>180	1	0
Median duration of cry	46.4 sec	32.3 sec

25D: 25% dextrose, EBM: Expressed breast milk

Table 2: Babies in the two groups with NIPS scores

NIPS Score	EBM group (%)	25D Group (%)
Mild Pain	11 (31.5)	19 (54.3)
Moderate Pain	17 (48.5)	12 (34.3)
Severe pain	7 (20)	4 (11.4)
Total	35	35

25D: 25% dextrose, NIPS: Neonatal Infant Pain Scale, EBM: Expressed breast milk

Table 3: NIPS scores of the 2 subgroups

Parameters	Finding	EBM group %	25D Group %	p value	Chi ² statistic
Facial expression	Relaxed	12 (34.2)	14 (40)	0.621	0.245
	Grimace	23 (65.7)	21 (60)		
Cry	No cry	8 (22.8)	9 (25.7)	0.5	1.03
	Whimper	13 (37.1)	16 (45.7)		
	Vigorous cry	14 (40)	10 (28.5)		
Breathing patterns	Relaxed	17 (48.5)	21 (60)	0.921	0.337
	Change in breathing	18 (51.4)	14 (40)		
Arms	Restrained/relaxed	28 (80)	31 (88.5)	0.971	0.324
	Flexed/extended	7 (20)	4 (11.5)		
Legs	Restrained/relaxed	25 (71.4)	27 (77.1)	0.5	0.299
	Flexed/extended	10 (28.5)	8 (22.8)		
State of arousal	Sleeping	3 (8.57)	2 (5.7)	0.2	2.42
	Awake	21 (60)	27 (77.1)		
	Fussy	11 (31.4)	6 (17.1)		

score and significantly shorter duration of crying. A Cochrane systematic review exploring the analgesic effects of breastfeeding and supplemental breast milk showed a superior analgesic effect of breastfeeding and supplemental breast milk compared with placebo, positioning, or no intervention and a similar effect compared with sucrose [9]. A study done by Harrison *et al.* [10] to compare pain responses in late preterms during heel lances demonstrated that compared with breast milk, 25% glucose provided lower pain scores and reduced duration of cry. A 2014 study in a Turkish hospital showed that the facilitated tucking position is superior to the classical holding position in decreasing pain perception during immunization with Hep B [11].

A recent study found that oral 25D can be used as an adjunct to other proven analgesic measures at BCG vaccination [12]. A study by Goswami *et al.* [13] showed similar efficacy of direct breastfeeding and oral dextrose at the first DPT vaccination. In a study by Kaur *et al.* [14], it was concluded that the perception of pain intensity is less among the infants when vaccine is administered during breastfeeding. A study by Malngiang *et al.* [15] showed that oral glucose seems to be a better analgesic compared to EBM during skin pricking procedures.

Our study aimed to compare analgesic efficacy of EBM and 25D during the intramuscular injection with Hep B at birth. We found that both EBM and 25D are effective in reducing pain perception at immunization clinics, more so for the 25D group. These findings are in line with the study of Malngiang *et al.*, with similar results during skin prick procedures in neonates. Vigorous cry was seen in more neonates of the EBM group when compared to that of the 25D group.

Limitations of this study were as follows: Both late preterms and terms were included in the study, and appreciation of sweetness would possibly be different. Both the outcome variables in our study were subjective. The precise time till the cry ended was not clearly defined. The observer was not blinded to the intervention, increasing the risk of bias.

CONCLUSIONS

Both 25D and EBM appear to reduce the neonate's perception of pain. In our study, 25D was slightly better than EBM; however, the results were not found to be statistically significant.

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